DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 27 2011

Medax Unipersonale SRL
% Pekato Medical Supplies, Inc.
Mr. Flavio Tomassini
3016 N.W. 82nd Avenue
Miami, Florida 33122

Re: K092338
Trade/Device Name: Medax Biopsy System – Guns and Needles
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: May 23, 2011
Received: May 27, 2011

Dear Mr. Tomassini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K092338

Section 4 Indication for use and Statement

4.1 Indication for use

510(k) Number: K092338

Device name: Universal Duo. Intended use: to be used for histological biopsy on soft tissues.
Device name: Neoxus. Intended use: to retrieve bone marrow and bone samples from iliac crest.
Device name: Cage. Intended use: to retrieve bone marrow and bone samples from iliac crest.
Device name: Velox. Intended use: histological biopsy on soft tissues
Device name: Velox 2. Intended use: histological biopsy on soft tissues
Device name: Universal Plus. Intended use: histological biopsy on soft tissues.
Device name: Universal. Intended use: histological biopsy on soft tissues.
Device name: Perfectus. Intended use: aspiration bone marrow from sternum or iliac crest.
Device name: Lux. Intended use: histological biopsy on soft tissues
Device name: Lux 2. Intended use: histological biopsy on soft tissues
Device name: Hepax. Intended use: histological and cytological biopsies of soft tissue
Device name: FNA (Chiba /Quincke /Turner/ Westcott / Franseen). Intended use: Aspiration needle for cyto - histological biopsies on soft tissue.
Device name: Facile. Intended use: histological biopsy on soft tissues
Device name: Cesar. Intended use: histological biopsy on soft tissues
Device name: Nextage. Intended use: histological biopsy on soft tissues

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____

Nil R P Dyke for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092338